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BY ECF

Hon. Julien Xavier Neals, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

BY ECF & EMAIL

Hon. Faith S. Hochberg, U.S.D.J. (Ret.)
Special Master
80 United Nations Plaza, Suite 12F
New York, NY 10017

Re: ***Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd., et al.*,**
Civil Action No. 2:21-13087 (JXN) (JSA)

Dear Judge Neals and Judge Hochberg:

Our firm, along with Wilson Sonsini Goodrich & Rosati, represents Plaintiff Mylan Pharmaceuticals Inc. in this matter. We write to bring to the attention of the Court and the Special Master a recent decision in a parallel case to this one, *Blue Cross & Blue Shield v. Teva*, No. 5:22-cv-159 (D. Vt. Jan 22, 2024) ("*BCBS VT*"), that bears directly on issues raised by Teva in its Motion to Dismiss, as well as questions posed by Judge Hochberg at the December 12, 2023, argument on that Motion. We provided Judge Hochberg with the *BCBS VT* decision earlier this week, but now write to provide a summary of the relevant portions of that decision.

We write for the additional reason of alerting the Court and the Special Master to another recent decision, *Federal Trade Commission v. Syngenta Crop Protection AG*, No. 1:22-cv-828 (M.D.N.C. Jan. 12, 2024), in which that court rejected the application of the price-cost test for the very reasons Mylan has explained bar its application in this case.

1. ***Blue Cross & Blue Shield v. Teva*, No. 5:22-cv-159 (D. Vt.)**

On Monday, January 22, 2024, Judge Geoffrey Crawford of the United States District Court for the District of Vermont ruled on Teva's motion to dismiss the complaint filed by Blue

Cross & Blue Shield of Vermont ("BCBS VT"). Though the court partially granted and partially denied the motion, it denied it as to all aspects of the motion that are relevant to Mylan's case.

The substantive allegations in BCBS VT's complaint (filed a year after and borrowing heavily from Mylan's complaint) are nearly identical to those alleged by Mylan. Indeed, it concerns the *very same conduct*—Teva's exclusion of Mylan. And like Mylan, BCBS VT alleges an overall scheme on Teva's part to unlawfully maintain its monopoly over Copaxone and details how Teva delayed Mylan's approval through sham citizen petitions and patent litigations and then stymied Mylan's uptake through: (i) a coercive market shift from the 20mg dosage to the 40mg dosage; (ii) a series of exclusive dealing arrangements; (iii) a campaign of false representations; and (iv) illegal copay kickbacks. *BCBS VT* cannot be more on-point, and the Vermont court's analysis of these issues is particularly instructive for this case. For Your Honors' convenience, we briefly summarize the relevant holdings.

Noerr-Pennington

As in this case, Teva argued in Vermont that its campaign of sham citizen petitions and sham lawsuits was entitled to antitrust immunity under the *Noerr-Pennington* doctrine. The court concluded, however, that *Noerr-Pennington* immunity should not apply at the motion to dismiss stage of the case. Ex. A at 27. It noted that *Noerr-Pennington* is an affirmative defense (*id.* at 25), that "[p]laintiffs have no affirmative obligation to plead facts to show that the Noerr-Pennington doctrine does not apply," (*id.*) (quotation omitted), and that the applicability of the sham exception is a question of fact for the jury (*id.* at 28) (citing *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 310 (E.D. Pa. 2011) and *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, 358 F. Supp. 389, 394 (D.N.J. 2018)).[1] For purposes of the motion to dismiss, the court held that BCBS VT had plausibly alleged Teva's filings were shams under both the test for single petitions *and* the test for serial petitions. Like BCBS VT, Mylan has argued that Teva's baseless filings are shams under either test.

The court went further and rejected several other arguments Teva raised in that case that it has also raised here in connection with its *Noerr-Pennington* arguments. **First**, Judge Crawford applied the single-petition test and refused to draw an inference in Teva's favor that its 40mg suit against Mylan was not objectively baseless, observing that none of the adjudicators in that action (PTAB, district court, and Federal Circuit) found Teva's position to be a close case. *Id.* at 31-32. **Second**, the court considered Teva's entire series of filings and expressly rejected

[1] While the *BCBS VT* court identified *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, 2022 WL 17546949 (3d Cir. Dec. 9, 2022), as an example of a case placing the burden of disproving *Noerr-Pennington* immunity on the plaintiff, *Takeda* was an appeal from a grant of summary judgment and is therefore not instructive on how to evaluate pleadings on a motion to dismiss. Regardless, as a non-precedential opinion *Takeda* does not bind this court.

Teva's argument that the Third Circuit cases *AbbVie* and *Wellbutrin* foreclose application of the serial-petitioning rule in the Hatch-Waxman context. *Id.* at 32-33 ("This court interprets [*Wellbutrin*'s] analysis to mean that the design and intent of Hatch-Waxman bolstered the conclusion that the serial-petitioning exception did not apply *in that case*, not that Hatch-Waxman lawsuits are categorically exempt from the serial-petitioning exception.").[2] **Third**, the court rejected Teva's argument that its non-Hatch-Waxman suits were not part of the same series because they were "temporally and topically dispersed" and did not trigger 30-month stays. *Id.* at 35. And **fourth**, the court rejected Teva's argument that its eight citizen petitions were effectively one petition. *Id.* at 36-39. We note that, under either test, the reasoning of the district court in *BCBS VT* is on all fours with the legal and factual arguments Mylan has presented in its opposition to Teva's motion to dismiss its complaint.

Causation

Teva argued in *BCBS VT*, as it has argued here, that its sham patent litigations could not have delayed Mylan's entry because the 30-month stays expired before the FDA approved Mylan's ANDAs. The court also rejected this argument, finding no fatal causation defect in BCBS VT's complaint (which mirrors Mylan's). Ex. A at 43-44.[3] As the court explained, on a motion to dismiss it must draw reasonable inferences in the plaintiff's favor and it was reasonable to infer that the stays led the FDA to divert its resources away from Mylan's ANDAs and prioritize reviewing applications for other generic drugs. *Id.* at 42, 44.

The court also rejected Teva's suggestion that its citizen petitions could not have delayed Mylan's approval. Just as it has done in this case, Teva invoked 21 U.S.C. § 355(q)(1)(A) to argue that its citizen petitions could not have delayed FDA approval of Mylan's ANDAs. But the *BCBS VT* court rejected this argument, noted that "[p]laintiffs are not required to plead a response to every potential argument that Teva has raised," (*id.* at 42-43) (quotation omitted),

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[2] The court stated that one district court in the Third Circuit has interpreted *AbbVie* as holding that the serial-petitioning rule does not apply to Hatch-Waxman suits. *Id.* at 33 n.23 (citing *La. Health Serv. & Indem. Co. v. Janssen Biotech, Inc.*, 2021 WL 4988523, at *8 n.20 (D.N.J. Oct. 27, 2021)). But that case is entirely consistent with the position Mylan laid out in its recent letter on *Azurity v. Bionpharma*. As *Azurity* explains, *Wellbutrin* (on which *AbbVie* relies) only limits application of the serial petitioning rule to instances where a brand manufacturer sues multiple generics on the same drug. *See* Mylan's Jan. 5, 2024, ltr. at 3. That is exactly what happened in *Louisiana Health*, where Janssen filed a single lawsuit against multiple ANDA applicants alleging infringement of a single patent. *La. Health*, 2021 WL 4988523, at *2. No court, in the Third Circuit or elsewhere, has held that the serial-petitioning rule "categorically" does not apply where a brand files serial sham cases against the same generic, as Teva did to Mylan.

[3] *Azurity* reached the same conclusion. *See* Mylan's January 5, 2024, ltr. at 3.

and held it plausible to infer that the FDA does in practice delay approval of generics ANDAs while responding to citizen petitions (*id.* at 43) (noting other courts have reached the same conclusion); *see also* Mylan's Br. at 36 n.19 (citing additional cases in accord).

Market Shift

Like Mylan, BCBS VT alleges that Teva's effort to shift the market from the 20mg to the 40mg dosage was an anticompetitive component of its overall monopolization scheme. While the court concluded that Teva had not performed a "product hop" because it had not executed a "hard switch" (*i.e.*, complete withdrawal of the legacy 20mg product), the court recognized that a hard switch is not essential to BCBS VT's overall scheme claim. Ex. A at 51-52 (following the logic of *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 270 (D. Mass. 2017) and *In re HIV Antitrust Litig.*, 2023 WL 3088218, at *8 (N.D. Cal. Feb. 17, 2023)).[4]

Key to the court's reasoning was its observation that "withdrawal of an old product is not the only means of coercion." *Id.* at 52 (quoting *In re HIV*, 2023 WL 3088218, at *8); *see also* Mylan's Br. at 18 n.9. BCBS VT alleges that Teva coerced customers in at least three ways: by manipulating the price of its Copaxone products, by tying rebates on the 20mg and 40mg products, and by targeting prescribers in an "intense outreach campaign." *Id.* at 52. Mylan has alleged the very same three categories of conduct.[5]

The *BCBS VT* court also was "satisfied that considered together," this "combination of pricing the new 40 mg drug below the legacy 20 mg version, threatening to withhold rebates for the 20 mg version, and pressing prescribers to exclude new generic entrants from their orders is sufficient to constitute a claim of coercive conduct." *Id.* at 57. In reaching this conclusion, the court rejected Teva's reliance on *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394 (3d Cir. 2016) (holding the threat of lost discounts in that case was non-coercive) because *Eisai* did not involve an attempt to shift a market from an old product to a new one by tying the rebates on both products. *Id.* at 55. Teva has sought to rely on *Eisai* here, but it is just as inapplicable here as it is in Vermont.

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[4] Mylan has never alleged that Teva engaged in a product hop and has not pled a standalone product hop claim. *See* Mylan's Br. at 17 n.8; Compl. at ¶ 231 n.44. But like BCBS VT, Mylan alleges that Teva's coercive market shift is part of Teva's broader monopolization scheme.

[5] Mylan's Compl. at ¶ 10 (Teva priced the 40mg product below the 20mg and raised prices on the latter); ¶ 123 (Teva tied rebates on the 20mg and 40mg doses and threatened to withhold rebates if customers did not cover the 40mg); ¶¶ 126-27 (describing Teva's pressure campaign on physicians to switch from 20mg to 40mg).

In sum, recognizing the "factually intensive nature of the coercion analysis" (*id.* at 53), the court concluded that these "allegations about Teva's bare-knuckled defense of its monopoly position may be sufficient to support a factual determination at trial that patients were subjected to coercion in choosing between the brand and the generic versions of the drug" (*id.* at 57).

Having concluded that the allegations relating to Teva's efforts to delay generic entry and to shift the market alone provided a sufficient basis to deny Teva's motion to dismiss, Judge Crawford did not reach the remaining allegations of Teva's post-entry conduct designed to diminish generic uptake. *Id.* The court's choice to refrain from parsing the remaining allegations shows that it properly understood Teva's conduct constitutes a single scheme and that BCBS VT's monopolization claim relates to that scheme as a whole. In short, there is no need to analyze each component individually, and a conclusion that one component is anticompetitive is sufficient for the entire scheme claim to survive a motion to dismiss.

2. *Federal Trade Commission v. Syngenta Crop Protection AG*, No. 1:22-cv-828 (M.D.N.C.)

On January 12, 2024, Judge Thomas Schroeder of the Middle District of North Carolina denied two motions to dismiss in *FTC v. Syngenta*, in which the FTC accuses two dominant pesticide manufacturers of using anticompetitive loyalty discount programs to exclude generic competitors. Ex. B at *1.

At issue in *Syngenta* (as here) is whether price functions as "the clearly predominant mechanism of exclusion" behind Defendants' exclusive arrangements, warranting application of the price-cost test. The court held that the FTC sufficiently "alleged non-price mechanisms of exclusion to foreclose application of the price-cost test" on a motion to dismiss. *Id.* at *19. Specifically, the FTC alleged that the Defendants' monopolist status and market barriers exacerbate the exclusionary power of their loyalty programs, that Defendants coercively retaliated against disloyal customers, and that Defendants' rebate agreements resemble bundling. *Id.* at *17–18. The same logic applies here where Mylan similarly alleges non-price mechanisms of exclusion.[6]

Of particular relevance to the present case, *Syngenta* extensively analyzed two Third Circuit precedents—*ZF Meritor* and *Eisai*—and concluded that neither supported the

[6] *See e.g.*, Compl. ¶ 209 (discussing barriers to entry—and Teva's monopoly power, which Teva does not contest); ¶¶ 10, 12, 123-24, 126-27 (detailing Teva's coercion and its tied rebates resembling bundling); *see also, e.g.*, ¶¶ 17–19 ("Mylan could not compete regardless of Mylan's pricing . . . Even if a generic were to offer a better 'net' price," suggesting non-price means of exclusion); Compl. ¶ 165 (House Teva report discussing Teva's House Brand strategy); Compl. ¶¶ 5–6 (discussing Teva's multi-pronged scheme to exclude generics from the market).

Defendants' argument that the price-cost test necessarily applies to single-product loyalty discounts (Ex. B at *18) as Teva has argued. The court also rejected the argument (similarly raised by Teva) that single-year loyalty discount agreements would mandate application of the price-cost test. Ex. B at *19.

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We thank the Court for its consideration of this matter. Naturally, if the Court has any questions, we are available to respond at the Court's convenience.

Respectfully submitted,

/s *Jakob B. Halpern*

Jakob B. Halpern

/jbh

cc: Counsel of Record (by ECF)